

HCW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Subhashis Banerjee et al.
Serial No. : 10/623,076
Filed : July 18, 2003
Entitled : TREATMENT OF PULMONARY
DISORDERS USING TNF α
INHIBITORS

ART UNIT: 1644

EXAMINER: Not yet assigned

Attorney Docket No. BBC-201

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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August 11, 2005
date of mailing and signature

Lisa Rasmussen
Lisa Rasmussen

TRANSMITTAL LETTER

Sir/Madam:

Transmitted herewith are: ☒ Change of Attorney Docket Number and Change of Correspondence Address; ☒ An Information Disclosure Statement under 37 CFR §§ 1.56, 1.97 and 1.98; ☒ Form PTO-1449 Information Disclosure Statement; ☒ A photocopy of each reference cited; and ☒ An Acknowledgement Postcard; to be filed in the above-identified patent application.

FEE FOR ADDITIONAL CLAIMS

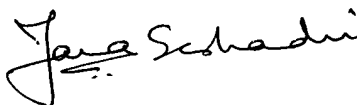
- ☒ A fee for additional claims is not required.
☐ A fee for additional claims is required. The additional fee has been calculated as shown below:

	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	NUMBER OF EXCESS CLAIMS	RATE	FEES DUE
TOTAL CLAIMS		65	0	× \$18	= 0.00
INDEPENDENT		20	0	× \$84	= 0.00
FIRST INTRODUCTION OF MULT. DEPENDENT CLAIM				+\$280	= 0.00
TOTAL FEES DUE					= 00.00

PETITION FOR EXTENSION OF TIME

- [] Extension is requested under 37 CFR 1.136(a), and the following extension fee is applicable for the paper(s) filed herewith: [] \$110.00 for response within first month pursuant to 37 CFR 1.17(a)(1);
[] \$430.00 for response within second month pursuant to 37 CFR 1.17(a)(2);
[] \$980.00 for response within third month pursuant to 37 CFR 1.17(a)(3);
[] \$1,530.00 for response within fourth month pursuant to 37 CFR 1.17(a)(4).
[] \$2,080.00 for response within fifth month pursuant to 37 CFR 1.17(a)(5).
- [X] The Commissioner is hereby authorized to charge payment of any additional fees required in connection with the paper(s) transmitted herewith, or to credit any overpayment of same, to **Deposit Account No. 010025**. A duplicate copy of this transmittal letter is transmitted herewith.

Respectfully submitted,



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Agent for Applicant
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Date


Lisa Rasmussen

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§ 1.56, 1.97 AND 1.98

Sir/Madam:

In accordance with the duty of disclosure under 37 CFR § 1.56, Applicants submit this Information Disclosure Statement pursuant to 37 CFR §§ 1.97 and 1.98 for the above-identified application. Applicants makes the following publications of record in the above-identified application.

U.S. Patent Documents

Salfeld et al., July 18, 2000, U.S. Patent No. 6,090,382

Salfeld et al., July 10, 2001, U.S. Patent No. 6,258,562

Salfeld et al., January 21, 2003, U.S. Patent No. 6,509,015

Foreign Patent Documents

Kempeni et al., December 19, 2002, WO 02/100330

Fischkoff et al., January 15, 2004, WO 2004/004633

Krause et al., February 26, 2004, WO 2004/016286

Kaymakcalan et al., May 6, 2004, WO 2004/037205

Salfeld et al., August 14, 1997, WO 97/29131

Other Publications

Agostini *et al.* (1996) *Am J Respir Crit Care Med.* 153:1359

Anticevich SZ, *et al.* (1995) *Eur J Pharmacol.* 284:221-5

Bingisser, *et al.* (1996) *Am J Respir Cell Mol Biol.* 15:64

Bowden, D.H. (1984) *Lab. Invest.* 50:487

Chadelat *et al.* (1998) *Eur Respir J.* 11:1329

Cohn, L., *et al.* (1997) *J. Exp. Med.* 186:1737

Coker *et al.* (1997) *Thorax.* Mar;52(3):294-6

Corbett EL, *et al.* (2002) *Am J Respir Crit Care Med.* 165:690-3

Deurloo, D.T., *et al.* (2001) *Am. J. Respir. Cell Mol. Biol.* 25:751

de Godoy *et al.* *Am J Respir Crit Care Med.* 1996 Feb;153(2):633-7

Hautmaki, R.D., *et al.* (1997) *Science* 277:2002

Hessel, E.M., *et al.* (1995) *Eur J Pharmacol.* 293:401

Hofstra, C.L., *et al.* (1999) *Inflamm. Res.* 48:602

Jones, P.W., *et al.* (1991) *Resp. Med.* 85(suppl):25

Keast, D.*et al.* (1981) *J. Pathol.* 135:249

Keatings, V.M. *et al.* *Am J Respir Crit Care Med.* (1996) Feb;153(2):530-4

Keatings VM. (2000) *Chest.* 118:971-5

Kips *et al.* (1992) *Am Rev Respir Dis* 145:332

Nash *et al.* *Histopathology.* 1993 Apr;22(4):343-7

Ordonez CL. *et al.* (2000) *Am J Respir Crit Care Med* 161:1185

Piquet *et al.* (1993) *Am J Pathol* 143:651

Piquet *et al.* *Eur Respir J.* 1994 Mar;7(3):515-8

Piquet *et al.* *Nature.* 1990 Mar 15;344(6263):245-7

Piquet *et al.* (1989) *J Exp Med.* 170:655-63

Pitsiou *et al.* (2002) *Respir Med.*;96(8):594-8

Ray *et al.* (1997) *J. Clin. Invest.* 100:2501

Other Publications cont.

Sakao *et al.* (2002) *Chest*. 122:416-20

Sakao *et al.* (2001) *Am J Respir Crit Care Med*. 163:420-22

Silver, R.M. (1995) *Int Rev Immunol*. 12:281

Smith *et al.* (1994) *J. Immunol*. 153:4704

Soler *et al.* *Eur Respir J*. 1999 Nov;14(5):1015-22

Takabatake *et al.* (2000) *Am J Respir Crit Care Med*. Apr;161(4 Pt 1):1179-84

Takeyama *et al.* (2001) *Am J Physiol Lung Cell Mol Physiol*. Jan;280(1):L165-72

Takeyama *et al.* (1999) *Proc Natl Acad Sci U S A*. Mar 16;96(6):3081-6

Thomas *et al.* (1995) *Am J Respir Crit Care Med*. 152:76-80

Thomas PS and Heywood G. (2002) *Thorax*. 57:774-8

Tokuda *et al.* (2000) *J. Immunol*. 164:2745

Vassallo *et al.* (2002) *Chest*. Sep;122(3):1093-6

Whyte *et al.* *Am J Respir Crit Care Med*. 2000 Aug;162(2 Pt 1):755-8

Zhang *et al.* *J Immunol*. 1993 May 1;150(9):4188-96

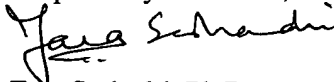
Form PTO-1449 listing each of these documents and photocopies of each document are enclosed herewith for the Examiner's convenience.

Applicants certify that each item of information contained in this Supplemental Information Disclosure Statement was first cited in a communication, International Search Report, received from a foreign Patent office, the Patent Cooperation Treaty, not more than three months prior to filing of this paper. Pursuant to 37 CFR §1.97(e)(1), no fee is required with this submission.

Applicant does not intend to represent that any of the documents submitted herein is material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicant respectfully requests that the documents submitted herein be considered and made of record in this application.

Respectfully submitted,



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Approved for use through 07/31/2006. OMB 0651-0031
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Substitute for form 1040/PTO

(Use as many sheets as necessary)

Application Number	10/623,076
Filing Date	July 18, 2003
First Named Inventor	S. Banerjee
Art Unit	1644
Examiner Name	Not yet assigned
Attorney Docket Number	BBC-201

Sheet	1	of	5
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		WO 02/100330	06-05-2002	Abbott Biotechnology Ltd.		
		WO 04/004633	04-24-2003	Abbott Biotechnology Ltd.		
		WO 04/016286	02-26-2004	Abbott Laboratories (Berm		
		WO 04/037205	05-06-2004	Abbott Biotechnology Ltd.		
		WO 97/29131	08-14-1997	BASF Aktiengesellschaft		

Date
Considered

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Complete if Known

Sheet	2	of	5	Application Number	10/623,076
				Filing Date	July 18, 2003
				First Named Inventor	S. Banerjee
				Art Unit	1644
				Examiner Name	Not yet assigned
				Attorney Docket Number	BBC-201

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Agostini et al. "Expression of Tumor Necrosis Factor-Receptor Superfamily Members by Lung T Lymphocytes in Interstitial Lung Disease" (1996) Am J Respir Crit Care Med. 153:135	
		Anticevich SZ, et al. "Induction of Human Airway Hyperresponsiveness by Tumour Necrosis Factor-a" (1995) Eur J Pharmacol. 284:221-5	
		Bingisser, et al. "Apoptosis in Human Alveolar Macrophages is Induced by Endotoxin and is Modulated by Cytokines" (1996) Am J Respir Cell Mol Biol. 15:64	
		Bowden, D.H. "Unraveling Pulmonary Fibrosis: The Bleomycin Model" (1984) Lab. Invest. 50:487	
		Chadelat et al. "Expression of Insulin-like Growth Factors and Their Binding Proteins by Bronchoalveolar Cells from Children with and Without Interstitial Lung Disease" (1998)	
		Cohn, L., et al. "Induction of Airway Mucus Production by T Helper 2 (Th2) Cells: A Critical Role for Interleukin 4 in Cell Recruitment but not Mucus Production" (1997) J. Exp.	
		Coker et al. "Anticytokine Approaches in Pulmonary Fibrosis: Bringing Factors into Focus" (1997) Thorax. Mar;52(3):294-6	
		Corbett EL, et al. "Polymorphisms in the Tumor Necrosis Factor-a Gene Promoter may Predispose to Severe Silicosis in Black South African Minors" (2002) Am J Respir Crit Care Med	
		Deurloo, D.T., et al. "CTLA4-IgG Reverses Asthma Manifestations in a Mild but Not in a More "Severe" Ongoing Murine Model" (2001) Am. J. Respir. Cell Mol. Biol. 25:751	
		de Godoy et al. "Elevated TNF-a Production by Peripheral Blood Monocytes of Weight-losing COPD Patients" Am J Respir Crit Care Med. 1996 Feb;153(2):633-7	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Sheet 3 of 5	Application Number	10/623,076
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		Hautmaki, R.D., et al. "Requirement for Macrophage Elastase for Cigarette Smoke-Induced Emphysema in Mice" (1997) Science 277:2002	
		Hessel, E.M., et al. "Bronchoconstriction and Airway Hyperresponsiveness after Ovalbumin Inhalation in Sensitized Mice" (1995) Eur J Pharmacol. 293:401	
		Hofstra, C.L., et al. "Antigen-stimulated Lung CD4+ Cells Produce IL-5, while Lymph Node CD4+ Cells Produce Th2 Cytokines Concomitant with Airway Eosinophilia and Hyperrespons	
		Jones, P.W., et al. "The St. George's Respiratory Questionnaire" (1991) Resp. Med. 85(suppl):25	
		Keast, D. et al. "A Survey of Pathological Changes Associated with Long-term High Tar Tobacco Smoke Exposure in a Murine Model" (1981) J. Pathol. 135:249	
		Keatings, V.M. et al. "Differences in Interleukin-8 and Tumor Necrosis Factor- α in Induced Sputum from Patients with Chronic Obstructive Pulmonary Disease or Asthma" Am J Resp	
		Keatings VM. "A Polymorphism in the Tumor Necrosis Factor- α Gene Promoter Region May Predispose to a Poor Prognosis in COPD" (2000) Chest. 118:971-5	
		Kips et al. "Tumor Necrosis Factor Causes Bronchial Hyperresponsiveness in Rats" (1992) Am Rev Respir Dis 145:332	
		Nash et al. "Expression of Tumour Necrosis Factor- α in Cryptogenic Fibrosing Alveolitis" Histopathology. 1993 Apr;22(4):343-7	
		Ordonez CL. et al. "Increased Neutrophil Numbers and IL-8 Levels in Airway Secretions in Acute Severe Asthma" (2000) Am J Respir Crit Care Med 161:1185	

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		Piquet et al. "Requirement of Tumor Necrosis Factor for Development of Silica-Induced Pulmonary Fibrosis" Nature. 1990 Mar 15;344(6263):245-7	
		Piquet PF et al. "Tumor Necrosis Factor/Cachectin Plays a Key Role in Bleomycin-Induced Pneumopathy and Fibrosis" (1989) J Exp Med. 170:655-63	
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		Ray, P., et al. "Regulated Overexpression of Interleukin 11 in the Lung" (1997) J. Clin. Invest. 100:2501	
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		Sakao S, et al. "Association of Tumor Necrosis Factor α Gene Promoter Polymorphism with the Presence of Chronic Obstructive Pulmonary Disease" (2001) Am J Respir Crit Care Med	
		Silver, R.M. "Interstitial Lung Disease of Systemic Sclerosis" (1995) Int Rev Immunol. 12:281	
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		Soler et al. "Airway Inflammation and Bronchial Microbial Patterns in Patients with Stable Chronic Obstructive Pulmonary Disease" Eur Respir J. 1999 Nov;14(5):1015-22	
		Takabatake et al. "The Relationship Between Chronic Hypoxemia and Activation of the Tumor Necrosis Factor- α System in Patients with Chronic Obstructive Pulmonary Disease" (200	
		Takeyama et al. "Activation of Epidermal Growth Factor Receptors is Responsible for Mucin Synthesis Induced by Cigarette Smoke" (2001) Am J Physiol Lung Cell Mol Physiol. Jan;2	
		Takeyama et al. "Epidermal Growth Factor System Regulates Mucin Production in Airways" (1999) Proc Natl Acad Sci U S A. Mar 16;96(6):3081-6	
		Thomas PS, et al. "Tumor Necrosis Factor- α Increases Airway Responsiveness and Sputum Neutrophilia in Normal Human Subjects" (1995) Am J Respir Crit Care Med. 152:76-80	
		Thomas PS and Heywood G. "Effects of Inhaled Tumor Necrosis Factor α in Subjects with Mild Asthma" (2002) Thorax. 57:774-8	
		Tokuda, A., et al. "Pivotal Role of CCR1-Positive Leukocytes in Bleomycin-Induced Lung Fibrosis in Mice" (2000) J. Immunol. 164:2745	
		Vassallo et al. "Clinical Responses of Rheumatoid Arthritis-Associated Pulmonary Fibrosis to Tumor Necrosis Factor- α Inhibition" (2002) Chest. Sep;122(3):1093-6	
		Whyte et al. "Increased Risk of Fibrosing Alveolitis Associated with Interleukin-1 Receptor Antagonist and Tumor Necrosis Factor- α Gene Polymorphisms" Am J Respir Crit Care Me	
		Zhang et al. "Enhanced IL-1 β and Tumor Necrosis Factor- α Release and Messenger RNA Expression in Macrophages from Idiopathic Pulmonary Fibrosis or After Asbestos Exposure" J I	

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